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10/647,613

08/25/2003

Justin M. Crank

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CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/647,613  
Filing Date: August 25, 2003  
Appellant(s): CRANK, JUSTIN M.

**MAILED  
MAY 23 2007  
GROUP 3700**

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David M. Crompton  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 11/21/2006 appealing from the Office action mailed 06/21/2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**NEW GROUND(S) OF REJECTION**

Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al (US 5,827,201) in view of Dobson (US 5,724,989).

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,827,201	SAMSON	10-1998
5,724,989	DOBSON	3-1998

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**PREVIOUS GROUND(S) OF REJECTION**

1. Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al (US 5,827,201) in view of Dobson (US 5,724,989).
2. For claims 1, 7, 10, 16, 19, and 26, Samson et al discloses the claimed invention, *including*: a medical guidewire 100 comprising a tapered elongate shaft 142 coupled to a helically disposed coil 148,188, *except* for comprising the composite coil of two different materials wherein the outer material is for example a radiopaque coating and has a larger Young's modulus than that of the inner material (which dictates that the moment of inertia with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil is greater than the moment of inertia with respect to an axis running through the centroid and parallel to the radial axis of the coil). (For clarification: the examiner notes for example the Young's modulus of a typical radiopaque coating, tungsten carbide, is equal to 450 – 650 GPa whereas the Young's modulus for the inner material, Nitinol, ranges from 28 – 75 GPa depending upon stressed state of the crystalline structure which dictates either an austenite or martensite phase.) Dobson

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teaches a helically disposed coil 14 disposed on a the elongate tapered shaft 22 of a guidewire, wherein the wire forming the coil is comprised two different materials 30,32 wherein the outer material is for example a radiopaque coating 30 and has a larger Young's modulus than that of the inner material 32 (column 3 line 25 – column 4 line 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intravascular device as taught by Samson et al, with the composite wire coil of Dobson for the purpose of configuring the material and mechanical properties of an intravascular device to increase the efficacy of the device to navigate tortuous vasculature to increase patient safety during advanced surgical procedures.

3. For claims 2, 9, 11, 18, 21, 22, 28, and 29, Samson et al discloses a wire of polygonal and rectangular cross section (column 9 lines 54-58).

4. For claims 5, 14, 25, and 32, Dobson discloses wire formed of material with a Poisson's ratio ranging from 0.25 – 0.5. (For clarity: the examiner notes for example the Poisson's ratio of Gold is equal to 0.42 and that of AISI 304 Type Stainless Steel is equal to 0.29).

#### **NEW GROUND(S) OF REJECTION**

5. Claims 1, 2, 5, 7, 9-11, 14, 16, 18, 19, 21, 22, 25, 26, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al (US 5,827,201) in view of Dobson (US 5,724,989). Samson et al discloses the claimed invention, including:

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- a medical guidewire (100,140) comprising a composite tapered elongate shaft (130,142,152) having a proximal region with a first outer diameter and a distal region having a second outer diameter smaller than said first outer diameter (column 5 lines 10-31, as best seen in Figures 1 and 4), and
- a helical coil member (112,132,146,148,158,178,188,206) formed from a wire (i.e. the wire that forms coil members 112,132,146,148,158,178,188, or 206, wherein the Examiner notes as broadly as claimed a single helically disposed ribbon is a coil and the braids of Samson comprise multiple coils or ribbons of metallic wire, column 9 lines 52-63) having a polygonal and rectangular cross section (column 9 lines 54-58), disposed along said elongate shaft at the distal end of the proximal region over at least a portion of the distal region, and extending from the distal end of the proximal region over at least a portion of the distal region (as best seen in Figures 4 and 6B), wherein said coil member has an inner diameter that is greater than said second outer diameter (as best seen in Figures 1 and 5),
- wherein said wire has the following geometric parameters:
  - a cross-section with a centroid;
  - a moment of inertia (hereinafter  $I_x$ ) with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil; and
  - a moment of inertia (hereinafter  $I_y$ ) with respect to an axis running through the centroid and parallel to the radial axis of the coil; and
- wherein  $I_x > I_y$  of the wire because it is a polygon, i.e. not symmetric, and more material is distributed away from the longitudinal axis (the x-axis) without less

material being distributed away from the radial axis (the y-axis) (see page 13 2<sup>nd</sup> paragraph – page 15 1<sup>st</sup> paragraph of the Appeal Brief filed 11/21/2006).

6. Samson et al discloses the claimed invention, except for explicitly disclosing (a) the wire having a Poisson's ratio ranging from 0.25 or 0.3 to 0.5 and (b) the wire being a composite wire having a cross section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis, and a wire radial axis parallel to the coil radial axis and the wire being a composite wire further comprising a first material with a first Young's Modulus (hereinafter  $E_1$ ) at the centroid and a second material having a second Young's Modulus (hereinafter  $E_2$ ) further away from the centroid along the wire radial axis, wherein  $E_1 < E_2$ .

7. Dobson teaches a helically disposed coil formed of a composite wire (14) disposed on a the elongate tapered shaft (22) of medical a guidewire, wherein (a) the wire (14) has a Poisson's ratio ranging from 0.25 or 0.3 to 0.5 () and (b) the wire is a composite wire (14) having a cross section with a centroid, a wire longitudinal axis parallel to the coil longitudinal axis, and a wire radial axis parallel to the coil radial axis and the wire is a composite wire further comprising a first material (32) with  $E_1$  at the centroid and a second radiopaque material (30) having  $E_2$  further away from the centroid along the wire radial axis, wherein  $E_1 < E_2$  because Dobson teaches the first material comprising stainless steel with  $E_1$  typically ranging between 195-210 GPa (see page 16 of the Appeal Brief filed 11/21/2006) and a second radiopaque material, e.g. tungsten (column 4 lines 48-57) where the  $E_2$  of tungsten typically ranges between 400-410 GPa, as is well known in the art.

8. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical guidewire as taught by Samson et al, with the medical guidewire as taught by Dobson for the purpose increasing the efficacy of the medical guidewire to navigate tortuous vasculature thereby increasing patient safety during advanced surgical procedures by configuring the material and mechanical properties of medical guidewire.

**(10) Response to Argument**

9. Applicant's arguments filed 11/21/2006 have been fully considered but they are not persuasive. Applicant argues neither Samson et al, Dobson, and/or Samson et al in view of Dobson teaches, suggests, or discloses

- (a) a coil comprising a wire having a polygonal or rectangular shape;
- (b) a composite wire comprising a first material with a first Young's Modulus (hereinafter  $E_1$ ) at the centroid and a second material having a second Young's Modulus (hereinafter  $E_2$ ) further away from the centroid along the wire radial axis, wherein  $E_1 < E_2$ ; or
- (c) a coil comprising a wire having a moment of inertia (hereinafter  $I_x$ ) with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil and a moment of inertia (hereinafter  $I_y$ ) with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein  $I_x > I_y$ .

10. Regarding Applicant's argument (a), as stated above Samson et al in view of Dobson teaches a helical coil member (112,132,146,148,158,178,188,206) formed from



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a wire (i.e. the wire that forms coil members 112, 132, 146, 148, 158, 178, 188, or 206) having a polygonal and rectangular cross section (column 9 lines 54-58), wherein as broadly as claimed a single helically disposed ribbon is a coil comprised of wire and the braids of Samson comprise multiple coils or ribbons of metallic wire (column 9 lines 52-63).

11. Regarding Applicant's argument (b), as stated above Samson et al in view of Dobson teaches a composite wire comprising a first material (32) with  $E_1$  at the centroid and a second radiopaque material (30) having  $E_2$  further away from the centroid along the wire radial axis, wherein  $E_1 < E_2$  because Dobson teaches the first material comprising stainless steel with  $E_1$  typically ranging between 195-210 GPa (see page 16 of the Appeal Brief filed 11/21/2006) and a second radiopaque material, e.g. tungsten (column 4 lines 48-57) where the  $E_2$  of tungsten typically ranges between 400-410 GPa, as is well known in the art.

12. Regarding Applicant's argument (c), as stated above Samson et al in view of Dobson discloses a coil comprising a wire having a moment of inertia (hereinafter  $I_x$ ) with respect to an axis running through the centroid and parallel to the longitudinal axis of the coil and a moment of inertia (hereinafter  $I_y$ ) with respect to an axis running through the centroid and parallel to the radial axis of the coil, wherein  $I_x > I_y$  of the wire because it is a polygon, i.e. not symmetric, and more material is distributed away from the longitudinal axis (the x-axis) without less material being distributed away from the radial axis (the y-axis) (see page 13 2<sup>nd</sup> paragraph – page 15 1<sup>st</sup> paragraph of the Appeal Brief filed 11/21/2006).

**(11) Related Proceeding(s) Appendix**

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

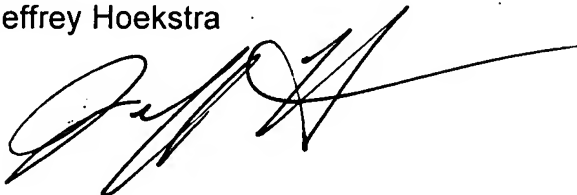
Extensions of time under 37 CFR 1.136(a) are not applicable to the **TWO MONTH** time period set forth above. See 37 CFR 1.136(b) for extensions of time to

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reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

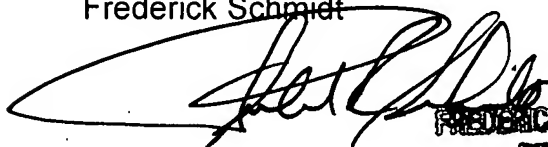
Respectfully submitted,

Jeffrey Hoekstra



A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Frederick Schmidt

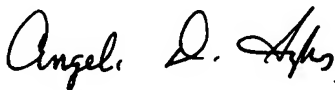
  
**FREDERICK R. SCHMIDT**  
**DIRECTOR**  
**TECHNOLOGY CENTER 3700**

Conferees:

Max Hindenburg



Angela Sykes



**ANGELA D. SYKES**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**